

Application No. 10/035,861  
Amdt. Dated July 12, 2005  
Reply to Office Action of April 13, 2005

### **REMARKS/ARGUMENTS**

#### **1. Remarks on the Amendment**

Claims 1, 14 and 24 have been amended to more specifically reflect Applicant's claimed method of detection of multiple test materials. The antecedent basis of the amendment can be found on page 9 lines 8-14 of the Specification as filed and in Claims 10, 12-13, 19 and 20 as filed. Applicant respectfully submits that no matter is added by the amendment.

#### **2. Response to the Double Patenting Rejections**

(1) Claims 1, 2, 6 and 14-15 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 5-6 of US 6,174,733.

(2) Claims 3-5 and 16-17 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 5-6 of US 6,174,733 in view of Lee et al (US 5,672,475).

(3) Claims 1, 2, 6 and 14-15 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 14-22 of US 6,337,214.

(4) Claims 3-5 and 16-17 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 14-22 of US 6,337,214 733 in view of Lee et al (US 5,672,475).

These rejections are respectfully traversed by the terminal disclaimers submitted together with this response.

Accordingly, Applicants request withdrawal of all rejections under the judicially created doctrine of obviousness-type double patenting.

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**3. Response to the Rejections of Claims 1-4, 6-16, 18-25 Based Upon 35 U.S.C. §102(e)**

Claims 1-4, 6-16 and 18-25 stand rejected under 35 USC §102(e) as being anticipated by Drmanac et al (US Patent No. 6,297,006). This rejection is respectfully traversed by the amendment.

Claims 1, 14 and 24 are independent claims, and Claims 2-13, 15-23 and 25 are dependent claims of Claims 1, 14 and 24, respectively.

For there to be anticipation under 35 U.S.C. §102, "each and every element" of the claimed invention must be found either expressly or inherently described in a single prior art reference. *Verdegaal Bros vs. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and references cited therein. See also *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1581, 230 USPQ 81, 84 (Fed. Cir. 1986) ("Absence from the reference of any claimed element negates anticipation."); *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). As pointed out by the court, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. *ATD Corp V. Lydall, Inc.*, 159 F.3d 534, 545, 48 USPQ 2d 1321, 1328 (Fed. Cir. 1998). See also *In re Spada*, 911 F.2d 705, 708, 15 USPQ ed 1655, 1657 (Fed. Cir. 1990).

As positively recited in the amended independent Claims 1, 14 and 24, Applicant's claimed method for detecting multiple test materials in a test sample requires a sequential analysis process in a test column having a plurality of snares which are spaced apart along a longitudinal axis of said column and separated one

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from another by an intervening air space. Applicant's claimed method includes steps of addition of a test sample, wash solution, a first probe and a second probe into the test column, wherein each of these described liquid materials passes through the plurality of snares from top down. This process allows each snare to be in contact with the same sample, the same probe and the same reagents.

Applicant submits that the claimed subject matter is not disclosed, taught or suggested by the art of record. More specifically, Drmanac et al fail to teach Applicant's claimed method which requires the sequential analysis process in a test column having a plurality of snares which are spaced apart along a longitudinal axis of said column and separated one from another by an intervening air space. On the contrary, Drmanac et al teach their analysis process using membrane to form arrays which consist of multiplicity of subarrays of dots, separated by a space between the dots (column 3, lines 64-67; and column 20, lines 28-59). Drmanac et al specifically teach that to prevent mixing of the probes between subarrays, a corresponding plastic, metal or ceramic grid may be firmly pressed to the membrane (column 20, line 66 to column 21, line 2). Drmanac et al further teach that an alternative approach is to use membranes or plates which is partitioned by physical spacers, such as a plastic grid molded over the membrane, or hydrophobic strips.

It is apparent that in Drmanac et al's method each sample has its specific location, i.e., a dot, or a subarray, on the membrane. The sample does not go through all snares (subarray in the prior art), as required in Applicant's invention. Furthermore, the probe and reagent for each subarray are not to be in contact with other subarrays or dots, instead, the probe and reagent are separated by plastic grid, or strips.

Therefore, the reference fails to anticipate or suggest Applicant's claimed invention defined by Claims 1, 14 and 24.

With regard to Claims 2-13, 15-23 and 25, as described above, these claims are dependent upon independent Claims 1, 14 and 24. Under the principles of 35 U.S.C. §112, 4<sup>th</sup> paragraph, all of the limitations of each independent claim are

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recited in its respective dependent claims. As described above, independent Claims 1, 14 and 24 are not anticipated by the prior art of record, as such Claims 2-13, 15-23 and 25 are submitted as being allowable over the art of record.

Accordingly, Applicant respectfully requests withdrawal of the rejection of Claims 1-4, 6-16 and 18-25 based upon 35 U.S.C. §102(e).

4. Response to the Rejections of Claims 5 and 17 Based Upon 35 U.S.C. §103(a)

Claims 5 and 17 stand rejected under 35 USC §103(a) as being unpatentable over Drmanac et al (US Patent No. 6,297,006) in view of Patel et al (US Patent No. 5,945,249). This rejection is respectfully traversed by the amendment.

Claims 5 and 17 are dependent claims of Claims 1 and 14, respectively. Applicant's claimed invention defined by Claims 1 and 14 have been described above.

A determination under 25 U.S.C. §103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. *In re Mayne*, 104 F.3d 1339, 1341, 41 USPQ 2d 1451, 1453 (Fed. Cir. 1997). An obviousness determination is based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and prior art; and (4) the objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966), see also *Robotic Vision Sys., Inc. v. View Eng'g Inc.*, 189 F.3d 1370 1376, 51 USPQ 2d 1948, 1953 (Fed. Cir. 1999).

In line with this standard, case law provides that "the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art." *In re Dow Chem.*, 837 F.2d 469, 473, 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). The first requirement is that a showing of a suggestion, teaching or motivation to combine the

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prior art references is an "essential evidentiary component of an obviousness holding." *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 USPQ 2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not "evidence." *In re Dembiczak*, 175, F.3d 994, 1000, 50 USPQ 2d 1614, 1617. The second requirement is that the ultimate determination of obviousness must be based on a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 903-904, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988); see also *In re Longi*, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ 2d 1780, 1783-84 (Fed. Cir. 1992).

The examiner has the burden of establishing a prima facie case of obviousness. *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ 2d 1210, 1214 (Fed. Cir. 1995). The burden to rebut a rejection of obviousness does not arise until a prima facie case has been established. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ 2d 1955, 1957 (Fed. Cir. 1993). Only if the burden of the establishing prima facie case is met does the burden of coming forward with rebuttal argument or evidence shift to the application. *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ 2d 1210, 1214 (Fed. Cir. 1995), see also *Ex parte Obukowicz*, 27 USPQ 2d 1063, 1065 (B.P.A.I. 1992).

As described before, nothing in the art of record teaches or suggests the subject matter positively recited in independent Claims 1 and 14.

Drmanac et al's teaching has been described above. Drmanac et al fail to teach Applicant's claimed method which requires the sequential analysis process in a test column having a plurality of snares which are spaced apart along a longitudinal axis of said column and separated one from another by an intervening air space.

Applicant respectfully points out that Drmanac et al teach away from Applicant's claimed invention.

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Applicant's claimed method includes steps of addition of a test sample, wash solution, a first probe and a second probe into the test column, wherein each of these described liquid materials passes through the plurality of snares from top down. This process allows each snare to be in contact with the same sample, the same probe and the same reagents.

On the contrary, using Drmanac et al's method each sample has its own specific location, i.e., a spot, or a subarray, on the membrane. The sample does not go through all snares (subarrays in the prior art), as required in Applicant's claimed invention. Furthermore, the probe and reagent for each subarray are not to be in contact with other subarrays or dots, instead, the probe and reagent are separated by plastic grid, or strips.

The deficiencies of Drmanac et al are not overcome by Patel et al.

Patel et al merely teach using acridinium dyes for an imaging media.

As described above, since Drmanac et al teach away from Applicant's claimed method, one ordinary skilled in the art will not be motivated to combine Patel et al's dyes with Drmanac et al's method to obtain Applicant's claimed invention. Even if one tries, in the manner suggested by the Examiner, one would not obtain Applicant's claimed invention.

Therefore, Applicant maintains that Applicant's claimed invention defined by independent Claims 1 and 14 is not obvious in view of prior art of the record.

As Claims 5 and 17 are dependent upon independent Claims 1 and 14, under the principles of 35 U.S.C. §112, 4<sup>th</sup> paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As discussed above, independent Claims 1 and 14 are not obvious in view of the prior art of record, as such Claims 5 and 7 are submitted as being allowable over the art of record.


Accordingly, Applicant respectfully requests withdrawal of the rejection of Claims 5 and 7 based upon 35 U.S.C. §103(a).

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It is respectfully submitted that Claims 1-25, the pending claims, are now in condition for allowance and such action is respectfully requested.

Applicant's Agent respectfully requests direct telephone communication from the Examiner with a view toward any further action deemed necessary to place the application in final condition for allowance.

7/12/2005  
Date of Signature

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